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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/019,100

08/21/2003

Zahir Saidi

P24,800-A USA

8648

7590

10/28/2008

Alexis Barron
Synnestvedt & Lechner
2600 Aramark Tower
1101 Market Street
Philadelphia, PA 19107-2950

EXAMINER

SOROUGH, LAYLA

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

10/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/019,100

Applicant(s)

SAIDI ET AL.

Examiner

LAYLA SOROUGH

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 11, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-9,10,13-21 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) 5,7-9 and 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,10,13-17 and 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2008 has been entered.

The original restriction election is carried over from the response to the office action mailed on August 10, 2006.

In view of applicants amendments to the claims a modified 35 U.S.C. 103(a) rejection is now made addressing the amended claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 10, 13-17 and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonne (US Pat No. 6,193,985— previously presented).

The invention reads on a composition consisting of: (a) from 5 ug/mL to about 5 mg/mL of a corticosteroid in dissolved form; (b) from about 0.1 to 20 percent by weight of a pharmaceutically acceptable, high-HLB surfactant component, wherein the HLB of the surfactants present in the high HLB surfactant component comprises at least 50%

Art Unit: 1617

by weight of an ethoxylated derivative of vitamin E, wherein said ethoxylated derivative of vitamin E is the sole vitamin E component of the composition; and (c) at least about 70 weight percent aqueous phase.

Sonne discloses an oil in water emulsion of budesonide as nose drop or nasal spray, comprising in the oily phase 0.025 grams of budesonide, 5 grams of vitamin e TPGS and 12.5 grams alpha-tocopherol – (viscous oil (surfactant)) (see col 3 line 18, col 11 Example 15). The limitation of the composition having at least about 70 weight percent of aqueous phase is met by the teachings of the water phase in the prior art (col 11 Example 15). Additionally, Sonne et al. teaches “Generally speaking compositions of the invention may contain from 1 to 99.99% (w/w), preferably 20 to 99.99%, most preferably 40 to 99.99% (w/w) of the tocopherol or tocopherol derivative solvent. The emulsion used in compositions of the invention may contain 1 to 95% (w/w) of the tocopherol or derivative thereof, preferably 20 to 95% (w/w), most preferably 35 to 80% (w/w) (Col 5 lines 55-61).” Sonne teaches “the formulations according to the invention may be optimized with respect to bioadhesion, sprayability and viscosity, as desired. Thus for example, the following co-solvents may be added: Vegetable oils such as sesame- or olive- or fractionated coconut oil, alcohols such as ethanol, propylene glycol, glycerol, polyethylene glycol or benzyl alcohol; or triacetin, (col 6 lines 47-59)” meeting the limitation of claims 15 and 17. Further, Sonne teaches “the tocopherol derivative emulsifier of the invention may be used alone or in conjunction with other known emulsifiers eg. phospholipids, polysorbates, sorbitan esters of fatty acids, cetearyl glucoside or poloxamers. It has furthermore surprisingly been shown that various other

solvents may be used in the emulsion system described above, without compromising the stability of the emulsion (col 4 lines 50-56)."

Sonne fails to exemplify a composition "wherein said ethoxylated derivative of vitamin E is the sole vitamin E component of the composition," or comprising a high-HLB surfactant component of at least 50%, 75%, 90% by weight tocopheryl polyethylene glycol 1000 succinate. Further, Sonne does not exemplify a composition containing from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable cosolvent comprising propylene glycol, polyethylene glycol having a molecular weight between about 200 and 4000, glycerol, ethoxydiglycol, glycofurol, and ethanol, or a combination thereof, 0.1 to about 3 percent by weight of phospholipids, nor 0.1 to about 3 percent by weight of an oil.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the composition by substituting the alpha-tocopherol of Example 15 with a vitamin e-TPGS and incorporating additional ingredients such as oils or alcohols inclusive of ethanol, propylene glycol, glycerol, polyethylene glycol or benzyl alcohol; or triacetin, or emulsifiers eg. phospholipids, polysorbates, sorbitan esters of fatty acids, cetearyl glucoside or poloxamers. The motivation to make such an incorporation is because Sonne teaches (1) it has been surprisingly found "that tocopherol derivatives, particularly certain esters, may themselves form efficient, non-irritating emulsifiers to enable stable emulsions to be formed, even where high lipid levels are involved eg. about 50-70%. Particular mention may be made in this regard of Vitamin E TPGS which is a water soluble derivative of Vitamin E and consists of .alpha.-

tocopherol, which is esterified with succinic acid, the other acidic group of the latter being esterified with polyethylene glycol 1000. Vitamin E TPGS is an almost odourless waxy amphiphilic substance with a molecular weight about 1513 (col 4, lines 27-35);" (2) the formulations according to the invention may be optimized with respect to bioadhesion, sprayability and viscosity, as desired. Thus for example, the following co-solvents may be added: Vegetable oils such as sesame- or olive- or fractionated coconut oil, alcohols such as ethanol, propylene glycol, glycerol, polyethylene glycol or benzyl alcohol; or triacetin and (3) the tocopherol derivative emulsifier of the invention may be used alone or in conjunction with other known emulsifiers eg. phospholipids, polysorbates, sorbitan esters of fatty acids, cetearyl glucoside or poloxamers. It has furthermore surprisingly been shown that various other solvents may be used in the emulsion system described above, without compromising the stability of the emulsion. Hence, the skilled artisan would have had reasonable expectation of successfully producing a composition that is non-irritating with optimized bioadhesion, sprayability, viscosity, without compromising the stability of the emulsion.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose range of the Sonne composition by routine experimentation (see 2144.05 11). The motivation to optimize the dose range of the Sonne 's final formulation is because one would have had a reasonable expectation of success in achieving the safest clinical outcome.

The composition "suitable for administering a therapeutic dose of a corticosteroid to the respiratory tract" is an intended use and does not receive patentable weight in a composition claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6, 10, 12-17, and 22-27 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6241969 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention herein is directed to a composition suitable for administering a therapeutic dose of a corticosteroid to the respiratory tract, consisting essentially of: (a) from about 5 ug/ml to about 5 mg/ml of a

Art Unit: 1617

corticosteroid in dissolved form, (b) from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable, high-HLB surfactant component, wherein the HLB of the surfactants is greater than about 10, and (c) at least about 70 weight percent aqueous phase whereas, the Patent is directed to an aerosolized composition for administering a therapeutic dose of a corticosteroid to respiratory tract, consisting essentially of: (a) from 5 ug/mL to about 5 mg/mL of a dissolved corticosteroid; (b) from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable, high-HLB surfactant component containing one or more surfactants having an HLB of greater than 10, wherein The high-HLB surfactant component comprises at least 50% by weight of an ethoxylated derivative of vitamin E; and (c) at least about 70 weight percent aqueous phase.

Response to Arguments

Applicant made no arguments to the rejections made on February 11, 2008.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax

Art Unit: 1617

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617